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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,885	04/13/2004	George R. Krsek	KONEC 04.02	5661

7590 06/14/2007

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,885	KRSEK ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments with respect to claims 1, 3-4 and 6 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. (U.S. Patent 5,869,498) in view of Guittard et al. (U.S. Patent 6,124,355).

Mayer et al. teach a pain-alleviating drug composition comprised of an opioid, such as oxycodone (Col. 3, lines 51-55) and a NMDA receptor antagonist such as dextromethorphan (Col. 4, lines 25-30). Compositions may be administered orally in the form of tablets or caplets (Col. 4, lines 64-67). Examples 10-11 show both capsules and tablets that are comprised of oxycodone hydrochloride and dextromethorphan hydrobromide. Mayer et al. further teachs polyvinylpyrrolidone as being added into the drug layer as a granulating fluid in making the tablets (Col. 7, lines 49-51).

Mayer et al. does not specifically teach that the tablets or capsules are comprised of two layers, an encapsulant disposed over the tablet, or the ratio of oxycodone HCl to dextromethorphan HBr.

Guittard et al. teach therapeutic compositions that include a second layer around the first layer that contains the active drug (Col. 4, lines 48-52). The second layer is comprised of a carboxymethylcellulose, an osmagent such as sodium chloride and a colorant such as ferric oxide (Col. 4, lines 52-67 – Col. 5, lines 1-4). Examples 2 and 3 show the preparation of the second layer. Guittard et al. further teach a subcoat to surround the bilayer that is surrounded by an outer semipermeable wall (Col. 5, lines 37-40). The dosage form comprises a passageway in the wall that connects the exterior of the dosage form with the internal compartment (Col. 5, line 67 – Col. 6, lines 1-5). Guittard et al. teaches magnesium stearate in both the first and second layers of the compositions (Examples 14 and 16).

Furthermore, it is obvious to vary and/or optimize the amount of oxycodone and dextromethorphan provided in the composition, according to the guidance provided by Mayer et al., to provide a composition having the desired properties such as the desired concentrations and ratios of active agents to produce the maximal analgesic effect. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly it would have been obvious to a person of ordinary skill in the art at the time of the invention, to combine the teachings of Mayer et al., which teach drug compositions comprised of oxycodone and dextromethorphan, with the teachings of Guittard et al. which teach therapeutic compositions that are comprised of a second layer that is comprised of carboxy methyl cellulose, sodium chloride and iron oxide.

Though Guittard et al. does not teach that the therapeutic composition is comprised of oxycodone and dextromethorphan, one would have been motivated to add a second layer comprised of carboxy methyl cellulose, sodium chloride and iron oxide to the pain-alleviating drug composition of Mayer et al. because this second layer will expand and occupy space in the compartment allowing the drug to be pushed from the dosage form and the first layer comprising the drug and the second layer act together to release the drug over time (as taught by Guittard et al.; Col. 5, lines 60-67).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER